510(k) Summary of Safety

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

K102684

Date Prepared:
May 17, 2010

OCT 1 2010

Submitter's Information: 21 CFR 807.92(a)(1)
Mr. Tristan Choi, Program Manager
INFINITT Co., Ltd.
12F Daerung Post Tower III,
182-4 Guro-dong, Guro-gu, Seoul,
152-050, Korea
Tel: +82.2.2194.6673
Fax: +82.2.2194.1698

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	XELIS DENTAL™
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Device Classification:	892.2050

Predicate Device: 21 CFR 807. 92(a)(3)

510(k) Number	K070464	K082990
Device Classification Name	system, image processing, radiological	system, image processing, radiological
Device Name	ONDEMAND3D	INFINITT XELIS
Applicant	CYBERMED, INC.	INFINITT CO., LTD.
Regulation Number	892.2050	892.2050
Classification Product Code	LLZ	LLZ
Decision Date	03/16/2007	11/20/2008
Classification Advisory Committee	Radiology	Radiology
Type	Traditional	Traditional

Device Description: 21 CFR 807 92(a)(4)

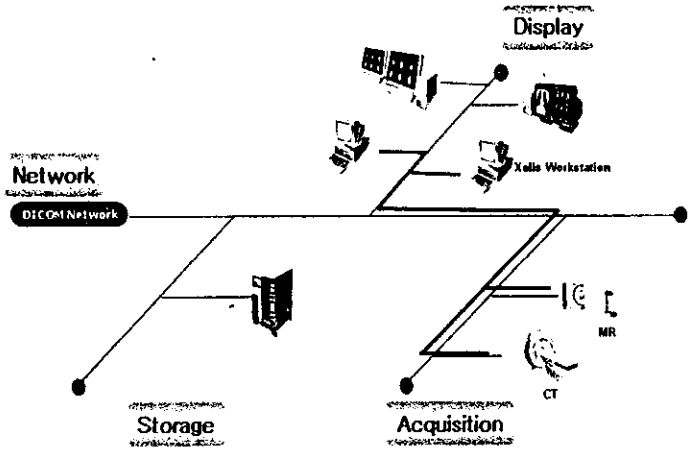
Xelis Dental is a PC-based application used for storing and displaying medical images. The application conforms to the DICOM 3.0 standard to allow interoperability with other DICOM compliant systems. The implementation of Xelis Dental DICOM interface has been carefully tested to assure compliance with the DICOM Conformance Statement. However, the Conformance Statement and the DICOM standard do not guarantee interoperability of INFINITT's products and products of other vendors. The user must compare the relevant Conformance Statements and if a successful interconnection should be possible, the user is responsible to specify an appropriate test suite and to validate the required interoperability. A network environment may need additional functions out of the scope of DICOM.

Xelis Dental provides viewing of optimized images for 3D dental CT images. It comprises the following features.

- 3D VR, MPR, MIP, minIP
- MPR rotating, curve, 3D zoom
- Nerve (canal) drawing

- Dental implant simulation and bone-density analysis

The subject device and the predicate devices are supplied to end users in both Windows 32 bit and 64 bit operations systems. XELIS DENTAL software can connect to other workstations, PACS server/software, and modalities, through the DICOM communication standard.



Indications for Use: 21 CFR 807 92(a)(5)

The Xelis DENTAL is a software device that is intended to provide tools for the reading and review of a DICOM compliant series of medical imagers which can be interpreted as representing a volume of data. These tools are meant for the use of trained medical imaging professionals to aid in their reading and review of such data.

Xelis DENTAL is intended for use as a software package which loads DICOM images from CT, MR, X-Ray, stores those and provides 3D visualization and 2D analysis, various MPR (Multi-Planar Reconstruction). These tools are meant for the use of trained medical imaging professionals to aid in their reading and review of such data.

Xelis DENTAL is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Technological Characteristics: 21 CFR 807 92(a)(6)

XELIS DENTALis a software device that does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians as an adjunctive to standard radiology practices for diagnosis. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Note: The subject device does not include any automated or semi-automated process for the detection of nodules or other shapes.

Nonclinical Testing:

The complete system configuration has been assessed and tested at the factory and has passed all in-house testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the XELIS DENTAL software in each operational mode and followed the process documented in the System Validation Test Plan. The nonclinical testing results are provided in the 510(k).

Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met. If the device is installed by INFINITT Co., Ltd, integration and installations verification tests are conducted against acceptance criteria prior to release to the client.

Conclusion: 21 CFR 807 92(b)(1)

The Pre-Market Notification for XELIS DENTALcontains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. Any differences between the predicate devices and the subject device are not significant since they do not raise any new or potential safety risks to the user or patient and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate devices. Therefore, XELIS DENTAL is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Infinitt Co., Ltd.
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

OCT 1 2010

Re: K102684
Trade/Device Name: Xelis DENTAL
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 16, 2010
Received: September 17, 2010

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102684

Device Name: Xelis DENTAL

Indications for Use:

Xelis DENTAL is a software device that is intended to provide tools for the reading and review of a DICOM compliant series of medical imagers which can be interpreted as representing a volume of data. These tools are meant for the use of trained medical imaging professionals to aid in their reading and review of such data.

Xelis DENTAL is intended for use as a software package which loads DICOM images from CT, MR, X-Ray, stores those and provides 3D visualization and 2D analysis, various MPR (Multi-Planar Reconstruction). These tools are meant for the use of trained medical imaging professionals to aid in their reading and review of such data.

Xelis DENTAL is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mark O'Hara for David Brown

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K102684